

AMENDMENTS TO SPECIFICATION

In the Specification

Please replace paragraph [0034] with the following amended paragraph:

[0034] The electrodes may be located such that the current from the ~~electrode~~ electrodes affects the growth plate to inhibit growth of the bone either permanently or temporarily. This location may be next to the growth plate, in close proximity to the growth plate, or directly in the growth ~~plat~~ plate to inhibit growth of the bone. The electrodes 16 may be inserted percutaneously or through other surgical procedures.

Please replace paragraph [0035] with the following amended paragraph:

[0035] The power source 12 and the controller 20 may be implanted within the patient or may be ~~keep~~ kept external. Keeping the power source 12 and controller 20 external allows for easy replacement of the power source and reprogramming of the controller. If the power source 12 and controller 20 are implanted in the patient, the controller may be preprogrammed prior to implantation. Further, the controller 20 may be programmable by wireless or other suitable communication from an external source, e.g., a computer.

Please replace paragraph [0037] with the following amended paragraph:

[0037] A method for inhibiting the growth of a bone includes placing one or more electrodes 16 within or in close proximity to the growth plate of the bone in which growth

is to be reduced or arrested. A current is applied to the growth plate through the implanted electrodes. The current should be high enough to inhibit, reduce, or stop bone growth of the treated bone. If the current is not high enough or the electrode is not positioned to apply current across the entire growth plate, growth of the bone will be reduced in the region where the current is applied, but the remainder of the bone will continue to grow resulting in uneven growth across the region of the bone. This may be desirable in the case of effecting disproportional growth such as that resulting in curves in bone, such as in the vertebral bodies of the spine. In other conditions and more typically, in limb length discrepancies, growth arrest or inhibition is required across the bone and ~~balance~~ balanced inhibition of growth across the bone is necessary.

Please replace paragraph [0039] with the following amended paragraph:

[0039] The invention includes a device and method for correcting the curvature of a spine. The method involves reducing the growth of a portion of one or more vertebrae located in the curving region of the ~~spin~~ spine. Specifically, the portion of the vertebrae located near the outside of the curving region is targeted for reducing or arresting growth of that portion of the vertebrae. The portion of the vertebrae on the inside of the curve is thus allowed to grow. As the portion of the vertebrae on the inside of the curving region of the spine grows, while the portion of the vertebrae on the outside of the curving region slows or stops, the curvature of the spine is reduced.

Please replace paragraph [0040] with the following amended paragraph:

[0040] With reference now to Figure 3, there is shown the device 10 discussed above configured for treating the curvature of the spine 40. In Figure 3, the device 10 includes ten leads 14 and ten electrodes 16. The number of leads and electrodes can be varied and is not particularly limited. The electrodes 16 are located at one or more vertebrae 42 in the curving region of the spine 40. The electrodes 16 are positioned near the outside of the curve of the spine. Preferably, the electrodes 16 are positioned starting at the vertebrae at the center or apex of the curve and are placed on adjacent vertebrae extending in both directions from the center or apex of the curve. The electrodes 16 are positioned such that the growth of the portion of the vertebrae 42 near the outside of the curve is slowed or arrested, without stopping the growth of the same vertebrae on the inside of the curve. Preferably, a small hole is made in the vertebrae 42 for receiving the electrodes 16. The electrodes 16 can remain permanently in place without complication much like the rods and implants in conventional surgical approaches, or the electrodes can be removed once the desired correction is achieved. The procedure requires operative placement of the electrodes from the multiple leads as required to each involved growth plate by thoracoscopy, thoracotomy, laparotomy, laparoscopy, or by radiographic or CT image guidance.

Please replace paragraph [0045] with the following amended paragraph:

[0045] According to an embodiment of the invention, performing a hemiepiphysiodesis in the spine may correct or lessen scoliosis or curves of the spine. If a curve can be created in the spine using current applied to the growth plate in the lateral or left aspect of multiple vertebral bodies, then the electrical current could be

applied to the apex of an existing curve and correct the curve or permit bone growth in the opposite direction. Figures 5 and 6 illustrate the result of an experiment using an Institutional Animal Use and Care Committee–approved protocol with an immature rabbit. The growth of the spine was tested to determine if it could be altered in a unilateral manner by placing electrodes unilaterally in the region of four epiphyseal plates of three vertebral bodies. Figure 5 illustrates the progress of the spinal curve created over the 6 weeks studied. The evidence from the x-rays strongly suggests that the growth of the spine is being affected by the unilateral current. After the 50 μ A in four vertebral growth plates for 6 weeks it is obvious that the spine is curving away ~~from~~ from the side where the current is delivered. In the control group the spine remains straight during this time frame (Figure 6). The x-rays are were digitized and the height of the vertebral bodies was measured. The percent change in the size of the right to left vertebra was found in the normal untreated spine to be between 0.992% – 1.015% while the vertebral size measured in the treated spine ranged from 2.5% to 9.5%.

Please replace paragraph [0046] with the following amended paragraph:

[0046] According to an embodiment of the invention a fine-thread electrode was inserted into a left distal femur and a power source was implanted subcutaneously in three groups. The three groups of subjects comprised those receiving [[,]] no current, those receiving a constant current of 10 μ A (low-current, LC), and those receiving a constant current of 50 μ A (high current, HC) and used modified OsteogenTM devices. At two weeks, the difference of femur lengths was measured with a digital caliper. Histologic changes were studied using hematoxylin-

eosin and Safranin-O staining, including narrowing of the growth plate or its possible closure, bony bridges, and the cellular arrangement of various zones in the growth plate. The computerized histomorphometric analysis of the growth plate was performed and comparisons were made in three groups and both the femur receiving current ("operated") and the femur not receiving current ("non-operated") limbs.